

## IRB Reviewer Checklist Expedited Initial Application

Revi	riewer: PRO#: PI Name:					
Regulatory Criteria for Approval						
In order to approve research covered by this policy, the IRB shall determine that all of the following						
requirements are satisfied:						
	Risks to participants are minimized by using procedures which are consistent Yes No					
	h sound research design and do no unnecessarily expose participants to risk.					
	Risks to participants are minimized whenever appropriate by using procedures		Yes	□No		
already being performed on the participants for diagnostic or treatment purposes.						
Risks to participants are reasonable in relation to anticipated benefits, if any, to			Yes	□No		
participants, and the importance of the knowledge that may reasonably be						
expected to result						
Selection of participants is equitable taking into account the purposes of the Yes   No						
research, the setting in which the research will be conducted, the special						
problems of research involving vulnerable populations, the selection criteria and						
other recruitment procedures.						
Informed consent will be sought from each prospective subject or the subject's			Yes	□No	□ NA	
legally authorized representative, in accordance with, and to the extent required						
	he regulations.					
	en appropriate, the research plan makes adequate provision for monito	oring	Yes	□No	□ NA	
	data collected to ensure the safety of participants.					
When appropriate, there are adequate provisions to protect the privacy of Yes No NA				□ NA		
participants and to maintain the confidentiality of data.						
When some or all of the participants are likely to be vulnerable to coercion or			Yes	□No	□ NA	
	undue influence, such as children, prisoners, pregnant women, mentally disabled					
	persons, or economically or educationally disadvantaged persons, additional					
safe	safeguards have been included in the study to protect the rights and welfare of					
these participants						
Reviewer: If you answered NO to any of the above, the Expedited review cannot be approved.						
IRB	Reviewer					
1	Risk: Minimal Risk					
2.	Consent Form Required Waived Consent					
3.	Child Assent: Not Applicable 12-17 years old < 12 years old					
4.	Transnational Research – The research protocols contains descriptions of and has complied with local					
	laws and customs Not Applicable Yes No					
5.	VA Medical Record Flag  Not Applicable  Required Waived					
6.	Regulatory Requirements of Subpart B and/or D Satisfied: Not A	Applicab	le 🗌	Yes	☐ No	
7.	Request for Expedited Review: Approved Refer to Full IRB					
8.	Expedited Review Categories:					
	For Category 1(a) and 1(b)					
	1(a) Confirm here that an IND is not required for use of the drug in this study.					
	1(b) Confirm here that and IDE is not required for the use of the device in this study.					
	1(b) Confirm here that the medical device is cleared/approved for marketing and the medical device is					
	being used in accordance with its cleared/approved labeling.					

9.	Continuing Review Required: Yes No				
10.	Comments:				
I certify that I do not have any conflict of interest related to this research or my review.					